Pendergast in view of Wang and Shames.

Claim 30 has been finally rejected as unpatentable under 35 USC 103(a) over Pendergast in view of Wang and Shames as also Fenton or Alianiello.

The examiner suggests: "If the applicant is certain that his structure as claimed will 'positively affect a contraction of the musculature of the foot, serving thereby to aid the venous outflow of blood,' then it will be clear that the structure of Pendergast will have the same effect."

RESPONSE

Claim 26, identifies a "sole base body" which defines certain areas, namely a "forefoot joint area," "a metatarsus/tarsus area," a "metatarsus/heel transition area," a "heel area,' and a"plantar arch area." One can argue that the soles of the prior art define such areas. However, they do not include the specific layers in these areas, namely a "first cushioned layer" located in the "forefoot joint area," a "second cushioned layer" located in the "metatarsus/tarsus area," and a "third cushioned layer" located in the "metatarsus/heel transition area." These layers are each divided into "plateau-like fields" which are "separated from but positioned next to each other in the transverse direction of said sole surface." These layers are "located at support areas.....which positively affect a contraction of the musculature of the foot serving to thereby aid the venous outflow of blood."

1) The teachings of Pendergast and Wang

Pendergast discloses a sole structure (orthodic device) which is defined as separated into segments (Fig. 1). None of the segments, however, are disclosed as having "cushioning layers" in specific areas , or that each is divided into "plateau-like fields" as is recited in claim 26. Pendergast is stated to be an orthodic device. That is it is concerned with the structure of the foot and its motion. Its stated purpose is not the blood vessels, that is it is not

concerned with blood vessel problems (phlebectasia).

Applicant cannot agree therefore that Pendergast "teaches all the limitations of claim 26 except....." It does not, it is respectfully submitted, teach any part of claim 26.

Wang discloses a plurality of encapsulated liquid cells at different locations. Wang is not at all analogous to the present invention or even to Pendergast. It certainly is a cushioning device, but it is so entirely different from either the present invention or Pendergast that, it is respectfully submitted, one of ordinary skill in the art would not even consult Wang for a phlebectasia problem.

The locations of the various cells are not very precise. That is, they are only generally located as shown and not specifically located. Whether or not they would because of their location have any effect on blood flow is not determinable from the disclosure.

2. The combination of Pendergast and Wang

The teaching basis for combining Pendergast and Wang is lacking in either Pendergast or Wang. A combination of the teachings of both would, at the very least, not suggest to one skilled in the art precisely where to locate the cushioning layers and what effect on blood flow this would have.

Regarding the above-noted statement of the examiner, it is respectfully submitted that the "functional language" should not be dismissed since it is defining, that is it further defines the structure of the cushioning layers because it relates a result which the cushioning layers were designed to accomplish. It is no different than any other structural feature which could be recited for the cushioning layers. It serves a distinguishing purpose and should be considered.

3. The remaining applied references

The Mauch, sawyer, Shames, Fenton and Alianiello patents each lack any

significant teaching regarding cushioning layers and their locations which one of ordinary skill in the art could use with either Pendergast or Wang to meet the limitations recited in claims 26, or claims 27-30 which depend therefrom.

4) Submission of paper and abstract

As noted above, submitted herewith is the paper and abstract which support applicant's reliance on the blood flow effect. Note the results noted on page 4 and the tables included on pages 5 and 6 for both men and women.

In the abstract a reported increase in the venous flow velocity is attributed to the sole of the present invention.

The examiner is urged to consider the above including the paper and abstract and to find claims 26-30 allowable.

Respectfully submitted,

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VenoPed – The shoe insole for the improvement of the venous reflux

Vein complaints, especially the varicose veins, are a national disease. 65% of all adults in Germany and in other industrial countries have morbid changes in their veins. Already amongst juveniles between the ages of 14 – 16 years is the venous system no longer healthy. Approximately 1.5 million people in Germany have an open leg. Due to vein diseases, the national economy loses yearly 13.000 working years. 7 billion DM is given out yearly by the health insurance companies for the treatment of vein diseases.

Varicose veins are usually traced back to a congenital, inherited weakness of the connective tissue. The consequences of the varicose vein disease when it is not timely treated are phlebitis, thrombosis, pulmonary embolism, swollen and open legs.

Varicose veins is a chronic disease which dynamically progresses over the years when untreated.

The above mentioned weakness of the connective tissue results to a weakening of the walls of the veins in the venous system of the leg. This leads to an incomplete closure of the valves of the veins thereby causing the blood in the veins to sink back into the leg since it is unable to flow completely upwards as it usually does - from the foot through the leg into the body. The peripheral venous pressure increases giving rise to congestion complaints, swollen legs, skin disorders and varicose veins which evolves into open legs when not treated on time.

Vein complaints can be significantly treated by accelerating the flow velocity of the upwards bound venous blood in the body.

The venous reflux can be increased through special gymnastics and the wearing of surgical stockings.

A rapid expulsion of the venous blood out of the stretched network of venous vessels of the foot is very important for the increment of the venous reflux. The vein gymnastics and the surgical stockings in this case contribute insufficiently.

The anatomy:

The vascular sole:

The sole of the foot consists of a tight and fine mesh-like network of superficial veins. These drain through the medial and fibula marginal vein into the saphena magna and saphena parva.

In the foremost region of the foot, these veins are connected through the subcutaneous venous plantar arch. The venous plantar arch drains into the dorsal plantar arch.

The deep veins of the foot (medial and lateral plantar vein) are connected to each other through the deep venous plantar arch and drain directly into the deep conduct veins (posterior tibial vein, fibula vein, anterior tibial vein) of the lower thigh. The valvelss perforans veins of the sole of the foot connect the deep and superficial veins of the foot with one another and participates, when the foot is under pressure, in the squeezing of the
sponge-like network of the sole of the foot. This vein network of the sole is one of the pressure-suctorial-pumps of the ankle- and gastrocnemius pumps. The supporting of this sole pumps of the foot accelerates the venous reflux in the leg.

The VenoPed shoe insole:

supports the muscle pumps of the foot and accelerates the evacuation in the venous network of the sole through special positionings. This results in a permanent stimulation of this sole region of the foot.

In contrary to surgical stockings, whereby perfusion disturbances are contraindicated, there are no hindrances in the application of the VenoPed insole.

Subjects:

25 women and 25 men were selected (compare tables). Before studies began, a clinical classification of the venous insufficiency was carried out on all subjects in conformity with the CEAP-classification (according to Porter and Moneta). Only subjects who could be categorised under the classification C1 (little varicose veins, no indication of an inherited varicose vein) were taken up for the study. The question of the so-called transfascial ostium insufficiency was initially ruled out through the use of Duplex sontopography. Also before the study began, through the usage of an oscillograph and Doppler sontopography, every subject was checked of an arterial blockage which results in a reduction of the arterial flow. Non of the subjects had been previously treated of diseases regarding their venous system. There existed no accompanying lymphoedemae. In each case, the state of the heart corresponded to the age and had no indication of pathological insufficiency.

There existed no restrictions in the mobility of the upper ankle of the subjects after measurements were taken according to the Neutral-Null-Method.

Method:

The flow velocity of the venous blood in the proximal superficial femoral vein distal to the ostium of the femoral vein profunda was measured with a colour-coded Duplex sontopography.

The wave angle lay between 40 and 60 degrees. The patients were measured while lying in a supine position with the upper part of the body elevated by 25 degrees and the legs placed in a slightly outwards-rotated position. The room temperature measured 20 degrees and there was no adaptation phase needed for the positioning.

Two measuring cycles were carried out. One measuring cycle to determine the flow velocity in the superficial femoral veins in the mornings and ten hours later after a normal daily routine. In the second cycle, a morning measurement was also carried out and a second measurement taken ten hours later after a normal daily routine wearing the VenoPed arch-support.

The subjects had different daily routines, predominantly standing, predominantly sitting as well as standing, sitting and walking normally.

Results:

On the average, after the wearing of the VenoPed shoe insole, there resulted an increase between 35% and 38% in the velocity of the venous reflux. Through this considerable increase of the venous reflux, the peripheral venous pressure is distinctly reduced.

For all vein diseases, which cause extreme restrictions of the haemodynamics, exists a distinct increase of the peripheral venous pressure which directly leads to the feared complex symptoms of the chronic venous insufficiency.

Hence, the VenoPed shoe insole contributes decisively to a timely positive influence of vein complaints particularly in the case of a non-manifested vein complaint.

VenoPed - Clinical study

Women

	Age	Flow velocity cm/s mornings in the quiet period	Flow velocity cm/s evenings after daily stress without VenoPed	Flow velocity cm/s evenings after daily stress with VenoPed
1	31	15	14	18
2	58	14	17	22
3	67	19	18	20
4	57	21	20	28
5	36	18	16	30
6	56	24	26	27
7	34	29	30	35
8	38	22	24	26
9	61	16	19	24
10	33	27	27	36
11	65	21	20	30
12	45	18	17	31
13	23	25	23	31
14	43	19	18	29
15	53	14	13	17
16	37	22	21	27
17	47	13	12	28
18	51	27	26	28
19	55	26	25	32
20	77	17	20	31
21	47	15	17	30
22	47	19	20	27
23	43	23	25	30
24	53	18	18	27
25	55	24	26	32

Average value		48,5	20,24	20,48	27,84
Average height		163,6cm			Increase in flow
Average weight		68,4			velocity by 35%

VenoPed - Clinical study

Men

	Age	Flow velocity cm/s mornings in the quiet period	Flow velocity cm/s evenings after daily stress without VenoPed	Flow velocity cm/s evenings after daily stress with VenoPed
1	53	21	20	29
2	57	24	25	28
3	56	17	17	22
4	48	16	18	30
5	71	19	16	21
6	60	17	16	25
7	40	29	25	37
8	44	31	30	39
9	63	21	22	32
10	60	16	17	26
11	45	16	14	29
12	47	27	25	37
13	22	28	29	37
14	39	30	28	41
15	48	32	31	34
16	38	18	19	24
17	32	27	26	35
18	56	15	17	20
19	61	12	10	22
20	44	16	15	24
21	58	11	13	17
22	58	23	21	30
23	67	18	19	30
24	46	22	23	28
25	25	27	29	33

Average value		49,5	21,32	21	29,2
Average height		169,8cm			Increase in flow
Average weight		76,7			velocity by 39%

14.WORLD CONGRESS OF THE UNION INTERNATIONALE DE PHLEBOLOGIE

INFLUENCE OF SEVERAL FOOT-MUSCLE PUMP SUPPORTING DEVICES ON THE VENOUS FLOW VELOCITY DURING A SCHEDULED WALKING PROGRAM

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Key words: venous flow rate, foot muscle pump, venous shoe insole, compression stocking, walking

The main principle in the treatment of the chronic venous insufficency is the augmentation of the venous flow velocity to reduce and/or prevent the well known problems resulting from the hypertonus of the peripherial veins. Walking which stimulates the foot muscle pump is the ideal sports activity for the veins. The sole of the foot consists of a tight and fine mesh-like network of veins which drain into the deep venous system and into the saphena magna and parva.During walking this foot muscle pump is squeezing this sponge-like network of these foot-sole veins and it comes to an acceleration of the venous flow velocity in the leg. We investigated the influence of a new muscle pump supporting device (shoe insole) on the venous flow rate in comparison with medical stockings of different categories(I,II)during a defined walking schedule with normal volunteers (Vena femor.superfic., Duplex technique, Woodway running-board).In the comparison without any supporting agent we found an acceleration of the venous flow velocity with this new developped shoe insole of 25-30%, with a compression stocking (I) of 20% and with a compression stocking (II) of 30%.
We conclude that this new shoe insole is an effective device to increase the venous flow velocity.